**ProjectXYZ - Clinical Trials Biomarker Testing - CompanyABC**

0:0:0.0 --> 0:0:7.210  
Cody Sole  
would you mind sharing a little bit about your professional backgrounds and experience related to biomarker testing?

0:0:8.280 --> 0:0:9.270  
Ernie Randolph  
Yes, sure.

0:0:9.380 --> 0:0:34.570  
Ernie Randolph  
I'm I'm a medical oncologist by training and I've been really focusing on drug development and oncology and related areas actually even in the neurosciences as I'm on the board of a neuroscience company that's performing global studies, but mainly in oncology, I've been I was in academics for about 12 years.

0:0:35.800 --> 0:0:37.590  
Ernie Randolph  
I participated in the.

0:0:38.210 --> 0:0:50.360  
Ernie Randolph  
This is before oncology was an interesting field and no one was involved, but I participated in and LED efforts to register over over 11 drugs in in my career.

0:0:51.620 --> 0:0:59.280  
Ernie Randolph  
I've been in industry for about 1516 years, starting with a M clone and then Mclone.

0:0:59.290 --> 0:1:1.140  
Ernie Randolph  
Lily is Lily acquired us.

0:1:2.740 --> 0:1:12.950  
Ernie Randolph  
So a lot of the targeted therapy, a lot of the genomics really became genomic testing, targeted therapy that requires companion diagnostics.

0:1:14.150 --> 0:1:16.710  
Ernie Randolph  
I've been involved with registering.

0:1:17.10 --> 0:1:47.280  
Ernie Randolph  
Drugs that required companion diagnostics for for industry over the last couple of years I've been more involved with consulting and I'm consulting CMO for companies that have developed Immunotherapeutics and everyone is kind of everyone has been sort of focusing on not only genomic biomarkers, but the last couple of years with the revolution and immunotherapy.

0:1:48.220 --> 0:1:48.690  
Ernie Randolph  
Umm.

0:1:49.60 --> 0:2:2.590  
Ernie Randolph  
Meaning that we have drugs that have become blockbuster drugs for the most part and have really modified the the way we we treat and not only treat, but we look at cancer.

0:2:2.760 --> 0:2:12.950  
Ernie Randolph  
I mean we, we, I twenty years ago, you would never thought the immune system played such a role where that you can modulate the immune system so that has and I'm.

0:2:13.20 --> 0:3:18.140  
Ernie Randolph  
I'm not trying to be tangential, I'm but, but that has actually really sparked another, umm harder, if you will of biomarker testing and companies. And that's really to monitor the immune system and to try to look for biomarkers that are relevant biomarkers in terms of picking patients who may be candidates for studies, umm, understanding who the best responders are from an immunological standpoint. And in addition monitoring Immunotherapeutics. So we've had like this revolution and and that's still occurring. I don't wanna really focus tremendously on biomarkers in terms of immune biomarkers umm, but there's also the genomic aspects sequencing and that that has really my talking too much.

0:3:20.740 --> 0:3:21.740  
Cody Sole  
No, I think that's great.

0:3:21.750 --> 0:3:22.860  
Cody Sole  
It's just please continue, yeah.

0:3:18.150 --> 0:3:27.750  
Ernie Randolph  
I'm sorry to shut me up. If you want me, but no. So so so sequencing. G hold.

0:3:27.790 --> 0:3:29.490  
Ernie Randolph  
Genomic sequencing.

0:3:29.640 --> 0:3:38.100  
Ernie Randolph  
Partial sequencing of genes that might be highly predictive of responses to certain drugs.

0:3:38.970 --> 0:4:20.410  
Ernie Randolph  
Umm we have incorporated that not only into drug discovery and into clinical trials, but it is now mainstream and it's incorporated into practice and you know with what? What what I'm also saying is with you know prices going down and and it will largely because of competition and because of the ease and the volume of material that flows into some of the companies where we're really seeing that. You know insurance companies are paying, they're not asking questions anymore. It's become you know, Genomic sequencing.

0:4:20.420 --> 0:4:45.400  
Ernie Randolph  
It's just become a mainstream thing that we do in cancer now, umm and and and not only that and heart disease and in, in and in, in neurosciences and I think neurosciences and oncology are I think neurosciences kind of the next growth spurt and a lot of neuroscience is you know it's very similar to oncology.

0:4:45.410 --> 0:4:47.530  
Ernie Randolph  
And I also want to talk about something else.

0:4:47.910 --> 0:5:7.650  
Ernie Randolph  
But umm, it used to be that, you know, we would do these big, big clinical trials like, you know, the cardiac, I mean I think the last one the you know studies of 10 to 20,000 patients and some of the you know cardiac or cardiopulmonary studies you know.

0:5:7.710 --> 0:5:23.550  
Ernie Randolph  
But I think that with the advent of biomarkers with that gives us is the ability to select the people who made robustly respond to to drugs.

0:5:24.220 --> 0:5:48.30  
Ernie Randolph  
So you know, for example, if you can identify a patient with with Alzheimer's disease who has a particular genomic marker where with ALS and you saw drug get approved actually just recently that has to genomic marker you, you you could easily get that drug approved.

0:5:48.120 --> 0:5:53.780  
Ernie Randolph  
I should, I should say more easily because you're you're efficacy results are so much better.

0:5:53.790 --> 0:6:5.730  
Ernie Randolph  
There are sort of, you know, unequivocally or irrefutable, and you, you might say, well, Gee, you know, you're restricting the patient population by doing that, but you're trials is smaller.

0:6:6.200 --> 0:6:31.330  
Ernie Randolph  
OK, your time from clinical discovery or development to registration is much faster because you can identify patients now and you could actually O get accelerated approval and and kind of O show not only regulators but also payers that you have a robust treatment.

0:6:31.420 --> 0:6:45.210  
Ernie Randolph  
And even though it's for a small proportion of patients or a smaller proportion of patients, you get your drug approved very quickly and it commands a premium price because the efficacy is so is so is so much greater.

0:6:45.220 --> 0:7:1.380  
Ernie Randolph  
And if you look at financial models, you know it even though you you're potentially cutting the population down substantially, you you could command the greater price and your compliance with physicians.

0:7:1.390 --> 0:7:8.280  
Ernie Randolph  
Physicians are gonna actually put more of a percentage of patients on that particular drug.

0:7:8.390 --> 0:7:13.140  
Ernie Randolph  
And so it becomes a very valuable, you know, your NPV's are higher.

0:7:13.150 --> 0:7:27.930  
Ernie Randolph  
And so, you know, I think we're living in an age and that's really genomics and and these companies have become very important, at least in the field that I work in, most commonly oncology sequencing.

0:7:28.320 --> 0:7:36.940  
Ernie Randolph  
And you know, those companies really include umm, you know foundation for example?

0:7:37.660 --> 0:7:47.0  
Ernie Randolph  
Tempus in a variety of other and, you know, aluminum is getting into the game and and you cardens is another one.

0:7:47.480 --> 0:8:0.390  
Ernie Randolph  
Umm, I'm sorry if I'm talking too much because I'm very excited about this field garden, you know, now you know, if you think about oncology here we are we we developed all these drugs and patients with advanced disease.

0:8:0.700 --> 0:8:4.860  
Ernie Randolph  
But the biggest impact, of course, is if we can prevent disease.

0:8:5.490 --> 0:8:15.230  
Ernie Randolph  
Yes, I'm not going to even talk about that because it's it's political, you know, you cut out the tobacco you and then, you know, tobacco and alcohol and you probably.

0:8:15.840 --> 0:8:20.710  
Ernie Randolph  
Umm, you know, cancer will go away for the most part and will and cardiac disease will.

0:8:20.830 --> 0:8:33.240  
Ernie Randolph  
So I I'm sorry and but but actually early detection and then we have companies like gardening that can and Illumina that could do liquid biopsies.

0:8:33.330 --> 0:8:54.610  
Ernie Randolph  
So you could actually find tumor DNA in the blood and not only not only find it in the blood, but find it in such small quantities that you know, screening now is becoming a reality.

0:8:54.840 --> 0:9:2.170  
Ernie Randolph  
You know mass screening because prices are low and we would really want to find disease early.

0:9:2.600 --> 0:9:15.270  
Ernie Randolph  
So I look at umm, you know the new the company that could sequent and the company center doing liquid biopsies and you know are ahead of the curve guard.

0:9:15.280 --> 0:9:29.430  
Ernie Randolph  
It now has the approval of an assay that when we reset the patient who has colon cancer and give them adjuvant chemotherapy, you know there's a 5060% chance that the tumor will come back.

0:9:29.820 --> 0:9:32.110  
Ernie Randolph  
Well, Garden has a test now.

0:9:32.500 --> 0:9:37.190  
Ernie Randolph  
That's the proof to screen for these high risk patients who may recur.

0:9:38.170 --> 0:9:41.120  
Ernie Randolph  
And you may say, well, what what?

0:9:41.130 --> 0:9:41.880  
Ernie Randolph  
What will that do?

0:9:41.890 --> 0:9:44.390  
Ernie Randolph  
If he's well, you might resect this patient again.

0:9:44.400 --> 0:9:45.960  
Ernie Randolph  
You may give them more time.

0:9:46.170 --> 0:9:53.340  
Ernie Randolph  
You might give them chemotherapy earlier and if you catch the disease early, you know there are things that you can do.

0:9:53.790 --> 0:10:2.330  
Ernie Randolph  
And I I just see this whole, I see this whole field changing really.

0:10:2.340 --> 0:10:4.320  
Ernie Randolph  
I mean, I'm very optimistic.

0:10:4.420 --> 0:10:30.410  
Ernie Randolph  
You know, I haven't been my entire life about new drug development until recently, when I see these tests and I really mean sequencing and and and there are many other companies that do other types of things that help us understand how a drug behaves and and and and who to select patients.

0:10:30.710 --> 0:10:42.970  
Ernie Randolph  
And those are companies that are focusing on protein nomics and I think you sent me two companies that that are at least one Carta that that does that I'm.

0:10:43.500 --> 0:11:5.220  
Ernie Randolph  
That's that, I think is a very difficult proposition, but Histology looking at looking at single cells and patients tumors we're in in disease and I see I see this field, I see I see drug development and and and I should say.

0:11:6.400 --> 0:11:7.160  
Ernie Randolph  
Medicine.

0:11:8.330 --> 0:11:19.280  
Ernie Randolph  
Revolutionizing because of these just development and we are working with these companies in almost every capacity.

0:11:20.610 --> 0:11:41.850  
Ernie Randolph  
I think you've listed some companies that are focused on immune therapy or immunoassays OI have to say that although we generally contract with many of the companies, some of which were on your list, that has really been a problem.

0:11:41.900 --> 0:11:43.250  
Ernie Randolph  
We haven't been able to find.

0:11:44.830 --> 0:12:3.10  
Ernie Randolph  
Parlous of drug responsiveness, as we have in the genomics or in the gene sequencing area, but I think that's because immunotherapy is like it and it's a virgin field.

0:12:3.110 --> 0:12:10.450  
Ernie Randolph  
So you know, if we looked at Genomics maybe 20 years ago, I think that's where we are with immunotherapy.

0:12:10.460 --> 0:12:11.530  
Ernie Randolph  
We're just, we don't.

0:12:11.570 --> 0:12:13.10  
Ernie Randolph  
It's so complicated.

0:12:13.910 --> 0:12:14.80  
Cody Sole  
Yep.

0:12:13.300 --> 0:12:16.710  
Ernie Randolph  
Or maybe we just don't understand it and we think it's complicated.

0:12:17.20 --> 0:12:19.280  
Ernie Randolph  
But we're looking for biomarkers.

0:12:20.160 --> 0:12:20.540  
Ernie Randolph  
OK.

0:12:20.550 --> 0:12:37.390  
Ernie Randolph  
So although we haven't found too many that are utilized by clinicians, except for maybe PDL 1 screening or microsatellite instability, which are highly predictive for work checkpoint inhibitor responsiveness.

0:12:38.530 --> 0:12:40.210  
Ernie Randolph  
Umm, we haven't found others.

0:12:48.140 --> 0:12:48.430  
Cody Sole  
Right.

0:12:41.270 --> 0:12:49.160  
Ernie Randolph  
So you know it, but we still use these technologies, we still use them in our trials because we're we're really certain.

0:12:49.860 --> 0:12:51.190  
Ernie Randolph  
So I'm gonna stop talking.

0:12:51.200 --> 0:12:52.430  
Ernie Randolph  
I've been going crazy here.

0:12:52.440 --> 0:12:53.0  
Ernie Randolph  
I'm so sorry.

0:12:53.830 --> 0:12:55.720  
Cody Sole  
O no, no, that's that's great.

0:12:55.730 --> 0:12:56.680  
Cody Sole  
Thanks for it.

0:12:56.750 --> 0:13:3.60  
Cody Sole  
Just educating us on this space and from what I understand, correct me if I'm wrong.

0:13:3.350 --> 0:13:5.760  
Cody Sole  
I'm definitely genomics growing a lot.

0:13:5.850 --> 0:13:12.320  
Cody Sole  
Along with immune monitoring and potentially a bit slow in the proteomics and histopathology space.

0:13:12.330 --> 0:13:18.540  
Cody Sole  
And that's and those are like pretty much for biomarker segments that we're considering.

0:13:18.930 --> 0:13:30.450  
Cody Sole  
And umm, I'm I'm wondering why you mentioned that you've used cell Carta, but you think it's pretty difficult proposition just.

0:13:30.510 --> 0:13:33.950  
Cody Sole  
Wanna follow upon understanding why you commented on that?

0:13:35.930 --> 0:13:38.470  
Ernie Randolph  
O I'm sorry that it's difficult.

0:13:38.610 --> 0:13:47.700  
Ernie Randolph  
Well, you know, I think CompanyABC and other companies like it that that are really focused on immunological assays.

0:13:49.130 --> 0:13:53.140  
Ernie Randolph  
Umm, or or histological assays.

0:13:53.990 --> 0:13:56.640  
Ernie Randolph  
I'm they're important in discovery.

0:13:57.90 --> 0:13:59.760  
Ernie Randolph  
OK, so you have a drug?

0:13:59.950 --> 0:14:8.190  
Ernie Randolph  
And these assays help us understand what the drug is doing to the tissue and which type of tissue could respond.

0:14:10.290 --> 0:14:10.790  
Ernie Randolph  
I mean not.

0:14:10.800 --> 0:14:16.330  
Ernie Randolph  
I mean, sorry, which types of tumors or which types of diseases might respond so we can select patients.

0:14:16.340 --> 0:14:18.760  
Ernie Randolph  
So we they're being used.

0:14:18.930 --> 0:14:24.590  
Ernie Randolph  
OK, so they're being used, but they haven't really been, you know, how should I say they have it.

0:14:38.770 --> 0:14:39.380  
Cody Sole  
Right.

0:14:24.660 --> 0:14:41.340  
Ernie Randolph  
These companies haven't brought us anything into I mean registrational or have served this computer diagnostics from a registrational standpoint because we just haven't found anything OK, that, that, that is, that is correct.

0:14:42.460 --> 0:14:42.970  
Ernie Randolph  
Yeah. Sorry.

0:14:39.470 --> 0:14:43.90  
Cody Sole  
I I guess the full got it.

0:14:43.160 --> 0:14:52.510  
Cody Sole  
So I guess the follow up question for that is what is your interest in using digital pathology as a companion diagnostic tool to?

0:14:52.760 --> 0:14:57.940  
Cody Sole  
Aid either patient selection or monitoring response.

0:14:59.350 --> 0:15:5.240  
Ernie Randolph  
Well, it it it certainly being digital pathology is is really pretty cool.

0:15:5.430 --> 0:15:5.980  
Ernie Randolph  
OK.

0:15:6.60 --> 0:15:12.970  
Ernie Randolph  
And I I will say that we are using digital pathology in in drug discovery.

0:15:13.370 --> 0:15:19.510  
Ernie Randolph  
So we're we're really looking and and not only in oncology, but in almost all fields, OK.

0:15:19.600 --> 0:15:27.960  
Ernie Randolph  
And I I really mean immunology, O immunology and neurosciences and and and those three are really the big one you know.

0:15:29.980 --> 0:15:41.530  
Ernie Randolph  
But but patient selection, it becomes a little cumbersome, although I have to say that there are trials that are using digital pathology for patient selection.

0:15:41.900 --> 0:15:47.850  
Ernie Randolph  
OK, it but it's more it's but but you have to have.

0:15:47.980 --> 0:15:49.640  
Ernie Randolph  
I mean I I shouldn't say for patient selection.

0:15:50.690 --> 0:15:57.680  
Ernie Randolph  
Umm, they're they're being used for as Carla, cause we're.

0:15:57.690 --> 0:16:3.100  
Ernie Randolph  
We're trying to look to see what on digital pathology correlates with response.

0:16:3.110 --> 0:16:5.420  
Ernie Randolph  
So I don't you know.

0:16:8.670 --> 0:16:8.870  
Cody Sole  
Uh-huh.

0:16:5.430 --> 0:16:10.250  
Ernie Randolph  
So they're being used in development, but they have Philly.

0:16:12.430 --> 0:16:22.880  
Ernie Randolph  
We really haven't drugs, we haven't had drugs that have shown that, that have correlated with an assay that is a digital pathology assay.

0:16:33.80 --> 0:16:33.720  
Cody Sole  
Right.

0:16:26.570 --> 0:16:34.960  
Ernie Randolph  
One it it's, it's an amazing tool because you could look at hundreds of different markers, you know utilizing and unique.

0:16:33.840 --> 0:16:35.40  
Cody Sole  
So umm.

0:16:35.390 --> 0:16:54.320  
Ernie Randolph  
And so it's being used, but the the other thing is like if you take oncology, I have a patient with a cancer and I I need I need to put that patient on treatment and digital pathology is there more, more for research.

0:17:0.950 --> 0:17:1.110  
Cody Sole  
Yeah.

0:16:54.330 --> 0:17:1.610  
Ernie Randolph  
You told it it it's very to return around very quickly, so it it.

0:17:1.680 --> 0:17:7.100  
Ernie Randolph  
It has some disadvantages, but nevertheless, you know, I think if there was a drug that.

0:17:7.220 --> 0:17:11.430  
Ernie Randolph  
Correlated with some some findings on digital pathology.

0:17:11.440 --> 0:17:12.270  
Ernie Randolph  
It'll get used.

0:17:12.280 --> 0:17:16.330  
Ernie Randolph  
It'll get approved and and that's just, you know, I think it'll come.

0:17:17.270 --> 0:17:17.720  
Cody Sole  
Right.

0:17:17.230 --> 0:17:18.140  
Ernie Randolph  
I know I I I.

0:17:17.760 --> 0:17:19.390  
Cody Sole  
So, umm.

0:17:19.430 --> 0:17:25.630  
Cody Sole  
And if I understand correctly sounds like it is a great tool to either explore.

0:17:25.690 --> 0:17:33.560  
Cody Sole  
Additional bone markers or as an add-on, potentially assay with other already either like genomic assays.

0:17:33.570 --> 0:17:39.970  
Cody Sole  
For example, I mean monitoring for the clinical trials, would you say that in five years?

0:17:39.380 --> 0:17:41.440  
Ernie Randolph  
Well, it's more than that.

0:17:41.500 --> 0:17:43.610  
Ernie Randolph  
It's more than that because there there.

0:17:43.680 --> 0:17:45.520  
Ernie Randolph  
OK, so not all drugs.

0:17:46.560 --> 0:17:52.50  
Ernie Randolph  
I'm you know like if you if you took cancers. You know, not all cancers have mutations.

0:17:52.350 --> 0:17:58.400  
Ernie Randolph  
You know, they don't have mutations that are activating the cancers for the not druggable mutations.

0:17:59.340 --> 0:18:8.190  
Ernie Randolph  
So there are so many other features of the cell or of the cancer cell that goes wrong, and digital pathology.

0:18:8.620 --> 0:18:11.830  
Ernie Randolph  
Could you know help us understand?

0:18:12.200 --> 0:18:17.730  
Ernie Randolph  
So what a drug is doing to a cell or so if you're so.

0:18:17.740 --> 0:18:22.280  
Ernie Randolph  
So we use digital pathology now in drug discovery.

0:18:23.170 --> 0:18:28.20  
Ernie Randolph  
So we're looking at, you know, a barren cells and where we could utilize.

0:18:28.150 --> 0:18:32.680  
Ernie Randolph  
I mean, there are digital pathology platform that are automated and high throughput.

0:18:33.560 --> 0:18:33.810  
Cody Sole  
Right.

0:18:33.60 --> 0:18:43.30  
Ernie Randolph  
So you can screen for many types of drugs using digital pathology and you get readouts that are just, you know, you.

0:18:49.80 --> 0:18:49.530  
Cody Sole  
Right.

0:18:43.80 --> 0:18:50.990  
Ernie Randolph  
You can do readouts that are, you know, pretty, pretty, complete of and and.

0:18:49.720 --> 0:18:59.470  
Cody Sole  
And understood, I guess I guess I was more wondering just the digital pathology utilization in the clinical space, let's say five years from now.

0:18:58.200 --> 0:19:1.540  
Ernie Randolph  
It it's it.

0:19:8.350 --> 0:19:8.560  
Cody Sole  
Mm-hmm.

0:19:1.550 --> 0:19:20.660  
Ernie Randolph  
It it's it's incorporated in clinical trials, but mainly as the search tool umm for you know as a retrospective search told not as a perspective search tool but this was what genomics was years ago.

0:19:21.430 --> 0:19:21.630  
Cody Sole  
Right.

0:19:21.550 --> 0:19:23.610  
Ernie Randolph  
I mean genomic testing.

0:19:23.830 --> 0:20:9.270  
Ernie Randolph  
So my my you, I I I think that you know studying protein, studying structure studying I think this is going to be very important and you have to start somewhere and it the the The thing is that we are using it I mean if if you look at you know companies that are doing Alzheimer's studies digital pathology is being utilized it's just not it's not at the forefront because we really haven't had the readout so it's being utilized in drug development but it's not commercialized as the as the tool that physicians use will it be I think it has a good chance of.

0:20:12.200 --> 0:20:12.460  
Cody Sole  
OK.

0:20:9.500 --> 0:20:15.250  
Ernie Randolph  
Of of doing so, yes, of of all the tools that I know, I think it's very important.

0:20:15.380 --> 0:20:32.30  
Ernie Randolph  
And it's also very important, you know, digital pathology, it it it's the the immune system, we're learning that it's not only the the, the cell that's apparent like the tumor cell in oncology, it's the, it's the entire environment.

0:20:32.890 --> 0:20:40.730  
Ernie Randolph  
So digital digital pathology allows us to look at the immune system that's in the tumor and that's that's very important.

0:20:40.780 --> 0:20:45.650  
Ernie Randolph  
So we're able to see cells that may be suppressing the tumor and the environment.

0:20:46.340 --> 0:20:49.720  
Ernie Randolph  
So we we're we're it's it's allowing us to make observations.

0:20:49.730 --> 0:20:57.680  
Ernie Randolph  
So we could potentially develop drugs and channel them to the right patient and then ultimately they will become a selection tool.

0:20:59.890 --> 0:21:0.350  
Cody Sole  
Right.

0:21:0.630 --> 0:21:2.460  
Cody Sole  
OK, now this clear.

0:21:2.590 --> 0:21:10.30  
Cody Sole  
I'm I'm I'm wondering is digital pathology used in liquid biopsies at all?

0:21:10.900 --> 0:21:25.120  
Ernie Randolph  
No, because the liquid biopsies liquid by, I mean you could you can you can view liquid biopsies and just take out cells, OK and then but usually the you know it's very hard you so.

0:21:25.130 --> 0:21:32.550  
Ernie Randolph  
So the way we we initially started with liquid biopsies is that we would look at cells that were floating around.

0:21:33.80 --> 0:21:34.760  
Ernie Randolph  
It's much easier now.

0:21:45.830 --> 0:21:46.50  
Cody Sole  
Right.

0:21:36.80 --> 0:21:46.810  
Ernie Randolph  
Find the DNA that's floating around, because a lot of tumors you don't have viable cancer cells that are floating around in the system and and and and.

0:21:47.40 --> 0:21:51.650  
Ernie Randolph  
And if you do often, those patients have highly, highly advanced disease.

0:21:52.660 --> 0:22:8.350  
Ernie Randolph  
So CT DNA, the the more we learn about mutations, I mean like umm alumina has a 700 minutes, maybe it's a little less than that 650 gene panel.

0:22:9.490 --> 0:22:19.930  
Ernie Randolph  
So one of those genes, I mean, none of those genes should be found in and non cancer setting.

0:22:20.320 --> 0:22:25.610  
Ernie Randolph  
So when you find it in a test, you know you draw blood and you find a mutated gene.

0:22:26.680 --> 0:22:29.830  
Ernie Randolph  
Umm for example, it has a K Ras mutation.

0:22:30.180 --> 0:22:33.490  
Ernie Randolph  
You don't find K Ras mutations in the in the normal body.

0:22:33.660 --> 0:22:35.380  
Ernie Randolph  
Something is going wrong somewhere.

0:22:36.170 --> 0:22:37.40  
Cody Sole  
Right. So.

0:22:36.160 --> 0:22:38.330  
Ernie Randolph  
That patient has tumor.

0:22:38.420 --> 0:22:42.730  
Ernie Randolph  
So, so, but, but but digital pathology can't be used.

0:22:46.340 --> 0:22:48.640  
Cody Sole  
And even for the liquids. I'm sorry.

0:22:48.680 --> 0:22:51.530  
Cody Sole  
Even like liquid based tumors like leukemia, lymphoma.

0:22:42.740 --> 0:22:53.510  
Ernie Randolph  
It's it's, it's it's really the sequencing and and and so I'm I'm not aware of that on.

0:22:53.620 --> 0:22:56.970  
Ernie Randolph  
Yeah, you could use it for but, but what do you use it for?

0:22:56.980 --> 0:23:37.120  
Ernie Randolph  
So you you know like what would you you you certainly leukemia lymphoma you. You certainly have cells that are in the peripheral blood and and don't get me wrong. I mean, there's solid tumors that you can find cells pretty easily such as prostate cancer if blood. It's a blood borne disease, but I I'm not. I'm not really. I I'm I. I don't I. I don't know if if people are using digital pathology to study those cells and and and we are doing you know, there's a whole new area technological area of single cell.

0:23:38.50 --> 0:23:42.990  
Ernie Randolph  
You know, RNA studies and you can look at what that cell is expressing.

0:23:43.750 --> 0:23:48.270  
Ernie Randolph  
I'm it just has it made it into the mainstream of drug development?

0:23:50.730 --> 0:23:51.820  
Cody Sole  
OK, sounds.

0:23:51.270 --> 0:23:57.540  
Ernie Randolph  
And I I I think sequencing is gonna be is gonna be a lot more revealing here.

0:23:58.510 --> 0:23:58.960  
Cody Sole  
Right.

0:23:59.150 --> 0:24:0.980  
Cody Sole  
And why do you say sequencing?

0:24:0.990 --> 0:24:13.20  
Cody Sole  
Uh, if we if we exclude the companion diagnostic part of it just for the regular bond micro testing clinical trial with patient samples, what specific sequence you're talking about?

0:24:13.30 --> 0:24:16.290  
Cody Sole  
Is it like in our DNA sequencing or whole exome sequencing?

0:24:16.470 --> 0:24:19.450  
Ernie Randolph  
Ohh so so right now DNA.

0:24:19.460 --> 0:24:29.80  
Ernie Randolph  
Because saying we got that well down, OK, so we we we really know umm, I mean the the tools that technology the sensitivity is gone up.

0:24:29.90 --> 0:24:45.820  
Ernie Randolph  
I told you about Guardian and alumina, but RNA sequencing is now starting to become I'm important as well and I'm there's a whole group of mutations and aberrations.

0:24:47.40 --> 0:25:0.570  
Ernie Randolph  
Umm that you won't see with DNA sequencing, but you will see with RNA sequencing like there's a whole bunch of things that happen in DNA but it doesn't get expressed in the RNA in the proteins.

0:25:1.960 --> 0:25:6.500  
Ernie Randolph  
I'm so studying the proteins and studying the M RNA.

0:25:6.510 --> 0:25:7.540  
Ernie Randolph  
What is expressed?

0:25:7.550 --> 0:25:21.250  
Ernie Randolph  
I mean the the most important thing is actually proteomics, because proteomics gives you kind of good understanding of what the cell is actually making to the MRI.

0:25:21.330 --> 0:25:26.100  
Ernie Randolph  
You know you can make, you can have a DNA aberration, but it's silent.

0:25:26.140 --> 0:25:27.380  
Ernie Randolph  
It doesn't do anything.

0:25:28.310 --> 0:25:28.550  
Cody Sole  
Right.

0:25:28.200 --> 0:25:28.620  
Ernie Randolph  
Umm.

0:25:29.710 --> 0:25:35.830  
Ernie Randolph  
If it makes them RNA, it's still may make M RNA, so the DNA is being expressed.

0:25:35.870 --> 0:25:40.990  
Ernie Randolph  
Sometimes that DNA is sometimes the the M RNA has the fusion in it.

0:25:41.790 --> 0:25:44.410  
Ernie Randolph  
I mean that I'm.

0:25:44.420 --> 0:25:44.850  
Ernie Randolph  
I'm sorry.

0:25:55.240 --> 0:25:55.550  
Cody Sole  
Hmm.

0:25:44.900 --> 0:26:0.330  
Ernie Randolph  
There's there's a an aberration called the Fusion that you will only see and only only see in M RNA, meaning can have a lot of fusions and DNA, but they may not be functional.

0:26:0.340 --> 0:26:2.840  
Ernie Randolph  
So the M RNA allows us to see functional.

0:26:4.160 --> 0:26:10.100  
Ernie Randolph  
Or to assess functional fusions, which are translated into proteins.

0:26:11.390 --> 0:26:13.660  
Ernie Randolph  
So this this is all.

0:26:16.650 --> 0:26:17.140  
Ernie Randolph  
Yeah.

0:26:17.230 --> 0:26:17.390  
Ernie Randolph  
Yeah.

0:26:12.710 --> 0:26:18.850  
Cody Sole  
The fusinus is that is that the same as translocation or other OK?

0:26:18.300 --> 0:26:23.270  
Ernie Randolph  
And you may have heard of two companies, you know, like Luxa was one of them.

0:26:23.280 --> 0:26:34.50  
Ernie Randolph  
I mean, it was bought by Lily for a couple of billion dollars on the basis of, you know, on finding a, uh, a drug.

0:26:34.140 --> 0:26:38.780  
Ernie Randolph  
That part gets a gene fusion that can only be seen.

0:26:37.930 --> 0:26:55.300  
Cody Sole  
O so right, so I guess full question on there is you know across let's say oncology clinical trials, how often does a trial use multi all mix kind of approach you assess DNA, RNA as well as protein together to understand?

0:26:56.370 --> 0:26:58.770  
Cody Sole  
Umm, you're as about market output.

0:27:1.830 --> 0:27:3.380  
Ernie Randolph  
Could could you say that again?

0:27:3.430 --> 0:27:4.820  
Ernie Randolph  
Can can you repeat your question?

0:27:22.170 --> 0:27:22.460  
Ernie Randolph  
Uh.

0:27:5.820 --> 0:27:23.380  
Cody Sole  
I wonder you know, if we look at all the clinical trials in oncology or just broadly how often does one trial one clinical trial use multiple approaches to assess DNA or RNA as well as protein together?

0:27:26.820 --> 0:27:35.80  
Ernie Randolph  
It doesn't happen very often, except good companies that have first in class molecules.

0:27:35.580 --> 0:27:36.450  
Ernie Randolph  
So I was.

0:27:36.620 --> 0:27:37.910  
Ernie Randolph  
I was recently.

0:27:38.380 --> 0:27:53.320  
Ernie Randolph  
I'm not with him anymore, but I was this CMO of a company called Hummingbird and we have an antibody Hummingbird nails in Singapore, but it's a drug.

0:27:53.500 --> 0:28:4.920  
Ernie Randolph  
It's an antibody discovery company and we were targeting a A an immunological checkpoint called Vista.

0:28:5.110 --> 0:28:5.620  
Ernie Randolph  
OK.

0:28:5.630 --> 0:28:20.330  
Ernie Randolph  
And we have no idea if this is gonna work in the clinic and we were looking at so many things in conjunction with a variety of of immunologic screening companies we were doing.

0:28:20.480 --> 0:28:24.750  
Ernie Randolph  
We were, we were doing umm digital pathology.

0:28:24.760 --> 0:28:26.280  
Ernie Randolph  
We were doing Multiplex.

0:28:26.720 --> 0:28:39.190  
Ernie Randolph  
Immunological studies on tissue. We were doing cytokine screening on on. On one side. Okines screening on and blood.

0:28:42.440 --> 0:28:42.680  
Cody Sole  
Uh-huh.

0:28:39.640 --> 0:28:46.550  
Ernie Randolph  
We were doing all link which is if I think you know is is a proteomic screening.

0:28:46.560 --> 0:28:50.510  
Ernie Randolph  
It's just very it's very and and we were just so.

0:28:50.520 --> 0:28:52.170  
Ernie Randolph  
So we were doing everything.

0:28:52.180 --> 0:28:54.30  
Ernie Randolph  
I mean, we were, but we're we're trying.

0:28:54.70 --> 0:28:55.250  
Ernie Randolph  
We were trying to look for.

0:28:56.670 --> 0:29:6.900  
Ernie Randolph  
We were trying to look for an effect because we have, it's a phase one trial and we're giving the drug and and and the drug may not be toxic.

0:29:6.910 --> 0:29:8.230  
Ernie Randolph  
We don't know where the dose.

0:29:8.740 --> 0:29:19.360  
Ernie Randolph  
So we were trying to look for a dose that could affect these biomarkers in a in a in a relevant way congruent with its mechanism.

0:29:20.90 --> 0:29:20.390  
Cody Sole  
Umm.

0:29:19.540 --> 0:29:26.50  
Ernie Randolph  
So companies like you know, the better companies that are developing a novel targeted therapy.

0:29:32.60 --> 0:29:32.300  
Cody Sole  
Right.

0:29:26.60 --> 0:29:34.190  
Ernie Randolph  
And I think those include the big companies that have deep pockets because it's very expensive.

0:29:34.660 --> 0:29:54.250  
Ernie Randolph  
But you know, like we were doing a lot of this at MDM person and MD Anderson has a lot of the the but we were paying fortune for it, which often goes to buy more equipment and but we were also farming a lot of this out to companies that do all all link and digital pathology etcetera.

0:29:54.800 --> 0:29:57.980  
Ernie Randolph  
But it's it's common.

0:29:58.270 --> 0:29:58.970  
Ernie Randolph  
It's common.

0:29:58.830 --> 0:30:0.540  
Cody Sole  
OK. OK.

0:30:6.540 --> 0:30:6.710  
Ernie Randolph  
But.

0:30:9.870 --> 0:30:11.810  
Ernie Randolph  
Ohh yeah, because you know it's often.

0:30:27.720 --> 0:30:28.550  
Cody Sole  
Right. So.

0:30:12.640 --> 0:30:31.570  
Ernie Randolph  
Yeah, because if it, especially in the immunological world or in the neuroscience world where you, you don't have a very good you, you have technology that allows you to look at effects, which I don't really have a good sense of the disease and and and and that's and and and and that's the issue.

0:30:32.230 --> 0:30:32.510  
Cody Sole  
Right.

0:30:32.520 --> 0:30:34.470  
Cody Sole  
And what you say sorry.

0:30:32.60 --> 0:30:36.310  
Ernie Randolph  
You know, we could we the sorry, go ahead.

0:30:35.570 --> 0:30:39.860  
Cody Sole  
I was just wondering why you say you know you don't have a good sense of the disease.

0:30:39.870 --> 0:30:49.530  
Cody Sole  
Are there particularly indications either in oncology or CNS require or you know large company prefer to use multiple approaches?

0:30:49.160 --> 0:30:51.580  
Ernie Randolph  
Oh, oh, yeah.

0:30:51.640 --> 0:30:55.590  
Ernie Randolph  
I mean, look, I Alzheimer's disease, OK?

0:30:55.600 --> 0:30:58.150  
Ernie Randolph  
So right now there's been.

0:30:58.210 --> 0:30:59.670  
Ernie Randolph  
OK, everyone's recording.

0:30:59.900 --> 0:31:14.460  
Ernie Randolph  
You know you can clear plaque, even amyloid, plaque, even in umm, you know, even in patients with it pre, you know, really prodromal Alzheimer's disease.

0:31:14.510 --> 0:31:15.220  
Ernie Randolph  
OK.

0:31:15.290 --> 0:31:28.940  
Ernie Randolph  
But the effect on cognition maybe pretty significant in some and even though you clear plaque, amyloid plaque and and and others, it may not affect that patient.

0:31:29.80 --> 0:31:37.900  
Ernie Randolph  
And if you look at other things they're going on in, in the brain, umm, there's Tao build up a towel proteins for example.

0:31:38.30 --> 0:31:40.480  
Ernie Randolph  
And there were a couple of other proteins that build up.

0:31:40.570 --> 0:31:44.200  
Ernie Randolph  
Are these primary effects, or are they secondary effects?

0:31:44.280 --> 0:31:47.360  
Ernie Randolph  
Is amyloid build up a primary effect?

0:31:47.690 --> 0:31:55.950  
Ernie Randolph  
I mean and and so if it were then clearing it out should really reverse the disease, but it doesn't.

0:31:56.380 --> 0:32:4.870  
Ernie Randolph  
It may in some patients, so even you know, even though we have this week, Lilly announced and you know we also Biogen.

0:32:4.880 --> 0:32:6.860  
Ernie Randolph  
And and Asai have drugs.

0:32:7.140 --> 0:32:12.750  
Ernie Randolph  
But we're still like, you know, we still don't understand the disease.

0:32:12.760 --> 0:32:17.180  
Ernie Randolph  
So incorporated into these phase three clinical trials and you bet?

0:32:17.300 --> 0:32:18.20  
Ernie Randolph  
It is.

0:32:18.430 --> 0:32:22.100  
Ernie Randolph  
There are so many marker studies to look at.

0:32:22.110 --> 0:32:40.680  
Ernie Randolph  
How to look at this to look at that, to look in the CNS in the fluid and and and so that is really where you know that's really where I'm good science is going and these very complex diseases that we really don't understand.

0:32:41.110 --> 0:32:47.760  
Ernie Randolph  
Neuroscience is like if you're going to do a neuroscience study, boy, you have to look at everything.

0:32:48.470 --> 0:33:12.410  
Ernie Randolph  
And I think you're science has and I think that those companies that do neuroscience studies use companion diagnostics and biomarkers and digital pathology a lot more than probably oncology the the, the, the, the other thing is that small companies that develop drugs don't have the deep pockets to use a lot of these technology.

0:33:13.90 --> 0:33:14.580  
Ernie Randolph  
You know they wanna get they wanna.

0:33:14.590 --> 0:33:17.60  
Ernie Randolph  
They wanna get to the races very quickly.

0:33:17.830 --> 0:33:18.110  
Cody Sole  
Right.

0:33:17.650 --> 0:33:21.520  
Ernie Randolph  
They they wanna finish their very quickly and they wanna get acquired.

0:33:21.650 --> 0:33:25.260  
Ernie Randolph  
But you know what Big Pharma is is very smart.

0:33:25.300 --> 0:33:32.680  
Ernie Randolph  
So Big Pharma is really looking at these biomarkers and Big Pharma has acquired companies on the basis of biomarker.

0:33:33.390 --> 0:33:34.940  
Ernie Randolph  
Modulation.

0:33:35.470 --> 0:33:42.160  
Ernie Randolph  
You know, as a surrogate for, you know, potential effect of a class of drugs.

0:33:42.270 --> 0:33:57.570  
Ernie Randolph  
So it really does make sense this small companies to take their time and incorporate these studies because that's, you know, you raised too quickly and you don't do these things and you don't get anywhere, you don't learn anything.

0:33:57.760 --> 0:33:58.410  
Ernie Randolph  
I'm sorry.

0:33:58.460 --> 0:33:59.940  
Ernie Randolph  
I'm going on a.

0:34:0.670 --> 0:34:2.660  
Cody Sole  
Yeah, I think that's that's definitely good.

0:34:2.670 --> 0:34:14.860  
Cody Sole  
Great point, but just wanna clarify what you mentioned and neuroscience or CNS in general is more likely to use digital pathology or genomics as companion diagnostics.

0:34:16.240 --> 0:34:21.0  
Ernie Randolph  
Hong Kong Agy and yes, and neurosciences and and autoimmune.

0:34:24.630 --> 0:34:24.850  
Cody Sole  
Right.

0:34:21.940 --> 0:34:25.530  
Ernie Randolph  
Those are the three areas it inflamma.

0:34:24.860 --> 0:34:27.990  
Cody Sole  
But but but.

0:34:28.100 --> 0:34:34.60  
Cody Sole  
But I think you said like CNS uses more than oncology, is that correct or maybe I was mistake?

0:34:32.680 --> 0:34:57.360  
Ernie Randolph  
Well, I I think I think so and and the reason why I think so is that I I think if you're a small company taking on oncology, you can kind of focus and and there's just a lot more small companies that are in the oncology space and they don't have deep pockets and they're they're really looking for fast, fast approval.

0:34:57.370 --> 0:35:10.200  
Ernie Randolph  
I mean, there's been this paradigm of companies getting acquired and exits and I and I also think that they don't have the money and they're they're primarily venture backed neuroscience companies are much larger.

0:35:10.530 --> 0:35:19.830  
Ernie Randolph  
Even the biotech companies are larger and the funding that's required is greater to at least I think.

0:35:19.880 --> 0:35:22.870  
Ernie Randolph  
And I think the diseases are more complex.

0:35:24.560 --> 0:35:24.830  
Cody Sole  
Yeah.

0:35:24.840 --> 0:35:25.70  
Cody Sole  
OK.

0:35:25.80 --> 0:35:25.680  
Cody Sole  
That makes sense.

0:35:24.490 --> 0:35:50.740  
Ernie Randolph  
I mean look and and and just as a director at Biogen, I know that we do so many companion diagnostic studies we look at so many biomarker when we do a study in multiple sclerosis, you know that we think we don't understand multiple sclerosis.

0:35:51.270 --> 0:35:51.520  
Cody Sole  
Uh-huh.

0:35:50.750 --> 0:35:56.60  
Ernie Randolph  
I mean, you know, we can and there's it's there.

0:35:56.70 --> 0:36:1.160  
Ernie Randolph  
There really is a pathology in this disease that's just so complex.

0:36:1.170 --> 0:36:3.900  
Ernie Randolph  
I mean, we have drugs for it, but we still don't understand.

0:36:4.170 --> 0:36:6.920  
Ernie Randolph  
You know, we have a whole panoply of drugs.

0:36:7.10 --> 0:36:8.560  
Ernie Randolph  
Who should get interference first?

0:36:8.570 --> 0:36:11.220  
Ernie Randolph  
Who should get a cortical steroid first?

0:36:11.360 --> 0:36:12.730  
Ernie Randolph  
Who should get tech credera?

0:36:12.740 --> 0:36:20.520  
Ernie Randolph  
Who should get some of the more toxic therapies that that are very robust in terms of their effect?

0:36:20.530 --> 0:36:21.190  
Ernie Randolph  
We don't know.

0:36:23.150 --> 0:36:23.330  
Cody Sole  
Yep.

0:36:22.40 --> 0:36:23.390  
Ernie Randolph  
Umm and I.

0:36:23.440 --> 0:36:57.40  
Ernie Randolph  
I wish we had ways to and we're we're looking and you know the same and ALS, we just had the drug approved and on the basis it's a 10%, it's 10% of a very rare disease and you can bet that in that study we we were looking at biomarkers, immunological effects and many of the the looking was screening like olink technology and Myrna technology and looking in the CNS for proteins and blah blah blah and an Alzheimer's, it's even more complex.

0:36:58.20 --> 0:36:58.240  
Cody Sole  
Right.

0:36:57.920 --> 0:37:6.390  
Ernie Randolph  
And and I I just think if you go in blindly with a new drug, you don't understand that patient and their pathology.

0:37:10.260 --> 0:37:10.620  
Cody Sole  
Yep.

0:37:6.540 --> 0:37:11.240  
Ernie Randolph  
You know you don't learn anything at the end of the day and and.

0:37:10.660 --> 0:37:11.240  
Cody Sole  
OK then.

0:37:11.290 --> 0:37:18.280  
Ernie Randolph  
And so I think I think neurosciences is really the next you know where I should say it's here.

0:37:22.450 --> 0:37:22.610  
Cody Sole  
Yep.

0:37:18.290 --> 0:37:39.120  
Ernie Randolph  
They're utilizing the tools that you're speaking about and and I guarantee you they will be utilized someday in the clinic because of the complexity of the disease and and like presenile dementia is not, is is, it's not one disease, it's 10th diseases.

0:37:39.170 --> 0:37:44.200  
Ernie Randolph  
So how do you identify, you know, these 10 subpopulations?

0:37:44.210 --> 0:37:45.540  
Ernie Randolph  
That's what we're trying to do.

0:37:45.630 --> 0:37:56.0  
Ernie Randolph  
You know, like like like in in oncology, we we there was there there are three categories of breast cancer like one is hormone receptor expression breast cancer.

0:37:56.10 --> 0:37:56.250  
Ernie Randolph  
OK.

0:37:56.260 --> 0:37:57.520  
Ernie Randolph  
We we have drugs for that.

0:37:57.610 --> 0:38:1.740  
Ernie Randolph  
We know that that's the cause of this, and then there's her too.

0:38:1.830 --> 0:38:3.840  
Ernie Randolph  
So her two drives answers.

0:38:3.850 --> 0:38:7.40  
Ernie Randolph  
We know it's a driver and we we can target it.

0:38:7.90 --> 0:38:11.260  
Ernie Randolph  
And then there's this big wastebasket called triple negative breast cancer.

0:38:11.270 --> 0:38:17.550  
Ernie Randolph  
What it means is we don't know what's driving this, but more and more we're chipping away at it.

0:38:18.40 --> 0:38:20.890  
Ernie Randolph  
So maybe in 5% of patients it's BRACA.

0:38:21.200 --> 0:38:21.650  
Ernie Randolph  
OK.

0:38:31.490 --> 0:38:31.750  
Cody Sole  
Yep.

0:38:21.660 --> 0:38:33.200  
Ernie Randolph  
Maybe in another 5% it's DNA repair and the only way we can understand this is by doing, you know, these screening studies that are often I'm.

0:38:33.210 --> 0:38:37.80  
Ernie Randolph  
I'm sorry if I'm gonna have to leave you in about about.

0:38:37.120 --> 0:38:42.900  
Ernie Randolph  
I'm sorry, I'm getting cold in about probably 5 minutes or 7 minutes.

0:38:42.810 --> 0:38:44.690  
Cody Sole  
OK. Yeah.

0:38:44.700 --> 0:38:47.540  
Cody Sole  
Uh, so I I do have a quick full of question on those.

0:38:47.550 --> 0:38:57.710  
Cody Sole  
When you utilize multiple all mixed data or approaches to analyze patient samples, how do you do data analysis?

0:38:57.720 --> 0:39:4.140  
Cody Sole  
And if you have any CRO that you're outsourced to to support data analysis part, that would be appreciated.

0:39:4.150 --> 0:39:5.360  
Cody Sole  
If you have any feedback on those.

0:39:6.590 --> 0:39:9.960  
Ernie Randolph  
I'm usually OK.

0:39:9.970 --> 0:39:21.920  
Ernie Randolph  
So we that's a very good question and I know at Hummingbird, we were trying to understand what we would do internal.

0:39:22.500 --> 0:39:29.290  
Ernie Randolph  
So we, we we we wanted to manage our own data and do our own manipulations.

0:39:29.330 --> 0:39:47.440  
Ernie Randolph  
So and this is a complex area, so there are there are companies and each of the companies that you know you spoke about or you listed in your at the companies that do only for example have their own bioanalytics for bioinformatics.

0:39:48.70 --> 0:39:53.370  
Ernie Randolph  
But you know, they're looking at one or two algorithms that may not be the algorithm that.

0:39:57.390 --> 0:40:6.220  
Ernie Randolph  
You've many of the data analytical programs that are out there are kind of biased towards what do you want.

0:40:6.410 --> 0:40:7.560  
Ernie Randolph  
You want people?

0:40:7.970 --> 0:40:33.290  
Ernie Randolph  
I think I think this is something that is currently being insourced, so if you're looking for companies doing that, I think smart biotech companies are saying, well, they're doing it one way and we need some more people who are going to, you know, maybe it's a I, you know, that are going to really take an unbiased approach and allow that unbiased approach to take us somewhere.

0:40:33.370 --> 0:40:39.930  
Ernie Randolph  
I think many of the other companies, the companies that do the technology, often will analyze the data.

0:40:41.960 --> 0:40:42.570  
Cody Sole  
OK.

0:40:42.620 --> 0:40:45.260  
Cody Sole  
And I guess, how important? Umm?

0:40:41.700 --> 0:40:47.140  
Ernie Randolph  
Umm, but five years from, you know, five has their own informatics speak.

0:40:47.640 --> 0:41:8.550  
Ernie Randolph  
Biogen has their own informed and I think that's really the way it should be that let the company do the technology and then you control how it's analyzed, because if something's analyzed as well, I I just think you you, you you go up the path that may be totally wrong.

0:41:8.900 --> 0:41:10.570  
Ernie Randolph  
You know, I don't know.

0:41:10.860 --> 0:41:12.860  
Ernie Randolph  
So I I'm I'm finding out.

0:41:11.180 --> 0:41:13.480  
Cody Sole  
So how much data analysis support I?

0:41:13.490 --> 0:41:14.860  
Cody Sole  
Guess I was just wondering.

0:41:14.870 --> 0:41:16.290  
Cody Sole  
This girl should provide.

0:41:19.370 --> 0:41:19.570  
Cody Sole  
OK.

0:41:17.580 --> 0:41:20.220  
Ernie Randolph  
They do, they they do.

0:41:20.290 --> 0:41:23.100  
Ernie Randolph  
But there it's their programs and they have their way of doing it.

0:41:25.510 --> 0:41:26.120  
Cody Sole  
Right.

0:41:25.550 --> 0:41:27.570  
Ernie Randolph  
And you know, but you have to have.

0:41:26.290 --> 0:41:38.570  
Cody Sole  
So even in the clinical trials for, let's say patients selection for genomics of loss at home and try you would analyze those data in health or it's only for the exploratory ones.

0:41:37.370 --> 0:41:48.0  
Ernie Randolph  
No, I we we would probably want someone in house who can analyze the data that's coming out of the CRO.

0:41:48.330 --> 0:41:53.310  
Ernie Randolph  
You you've mentioned a couple of easy tests like plus itry there.

0:41:53.320 --> 0:41:58.60  
Ernie Randolph  
There really aren't a lot of various ways to analyze those data.

0:41:58.70 --> 0:41:58.970  
Ernie Randolph  
I mean, you can turn.

0:42:0.170 --> 0:42:2.750  
Ernie Randolph  
He'll look at different channels, blah blah blah, but I don't.

0:42:3.880 --> 0:42:9.960  
Ernie Randolph  
But when you're dealing with you know omics I think protein Omics and M RNA expression.

0:42:9.970 --> 0:42:12.760  
Ernie Randolph  
There's so many different variations.

0:42:13.170 --> 0:42:17.260  
Ernie Randolph  
You know, we don't know what's one thing controls another, you know.

0:42:17.270 --> 0:42:19.480  
Ernie Randolph  
And that's that's a.

0:42:20.130 --> 0:42:33.940  
Ernie Randolph  
So I I do think that what we came, I know it at my former company we we concluded that we needed someone in House and there aren't too many of these experts around.

0:42:33.950 --> 0:42:34.960  
Ernie Randolph  
It's a big void.

0:42:35.860 --> 0:42:36.910  
Cody Sole  
Yeah, OK.

0:42:37.60 --> 0:42:38.490  
Cody Sole  
I I want to respect your time.

0:42:38.500 --> 0:42:41.230  
Cody Sole  
I wanna how many minutes do you have here?

0:42:41.240 --> 0:42:41.910  
Cody Sole  
Just wanna make sure.

0:42:42.370 --> 0:42:43.520  
Ernie Randolph  
To walk somewhere.

0:42:43.530 --> 0:42:47.240  
Ernie Randolph  
So I'm gonna be walking with when I talk to my dog here.

0:42:46.300 --> 0:42:49.10  
Cody Sole  
OK, OK.

0:42:49.660 --> 0:42:54.70  
Cody Sole  
Just one like I guess more bigger question around CRO.

0:42:54.80 --> 0:43:2.710  
Cody Sole  
Just if you can name your favorites CRO's in both oncology as well CNS space, that'll be great.

0:43:2.390 --> 0:43:8.710  
Ernie Randolph  
OK, you're talking about CRO that do companion diagnostic studies.

0:43:8.610 --> 0:43:11.30  
Cody Sole  
For Bama care testing in clinical trials.

0:43:11.120 --> 0:43:11.850  
Ernie Randolph  
Ohh.

0:43:11.860 --> 0:43:22.450  
Ernie Randolph  
I mean, I I'm focused primarily on genomics, so I, I mean my favorite is garden and Tempest.

0:43:23.600 --> 0:43:23.800  
Cody Sole  
OK.

0:43:23.70 --> 0:43:42.790  
Ernie Randolph  
And alumina, but I don't I think you would be you know and in in in umm immunological development there's just so many and I'm I'm kind of a little bit umm, I'm probably not the best person.

0:43:43.860 --> 0:43:46.170  
Cody Sole  
OK, that is fine.

0:43:46.180 --> 0:43:50.690  
Cody Sole  
I think you did check some of the CRO's when we sent out the Screener.

0:43:50.800 --> 0:43:52.420  
Cody Sole  
If you could just provide, uh.

0:43:50.710 --> 0:43:54.90  
Ernie Randolph  
Ohh II. OK good.

0:43:54.100 --> 0:43:54.830  
Ernie Randolph  
I'm sorry.

0:43:54.890 --> 0:43:55.120  
Cody Sole  
Yeah.

0:43:55.320 --> 0:43:56.170  
Ernie Randolph  
Sorry, I mean.

0:43:55.130 --> 0:44:0.420  
Cody Sole  
And if you could just provide your feedback or experience with those that will be helpful.

0:44:0.610 --> 0:44:3.270  
Cody Sole  
So we could start with precision for medicine, yes.

0:44:0.860 --> 0:44:3.320  
Ernie Randolph  
OK, precision. OK.

0:44:3.630 --> 0:44:4.190  
Ernie Randolph  
OK.

0:44:4.390 --> 0:44:6.770  
Ernie Randolph  
Well, let me tell you what I think about precision.

0:44:7.140 --> 0:44:7.710  
Ernie Randolph  
Umm.

0:44:8.50 --> 0:44:11.460  
Ernie Randolph  
Precision was is a company.

0:44:12.190 --> 0:44:16.540  
Ernie Randolph  
Umm, that was you.

0:44:16.550 --> 0:44:24.480  
Ernie Randolph  
Have had a great small CRO and then it did a merger with a companion diagnostic company in in Europe.

0:44:25.530 --> 0:44:29.620  
Ernie Randolph  
I've used them for I I used them for CRO.

0:44:29.630 --> 0:44:32.390  
Ernie Randolph  
They break for oncology for clinical.

0:44:35.240 --> 0:44:43.960  
Ernie Randolph  
Some of them, you know, they, they they're really very specialized and but I have to tell you that we're companion diagnostics.

0:44:44.250 --> 0:44:46.180  
Ernie Randolph  
I've had terrible experiences with them.

0:44:47.380 --> 0:44:50.210  
Ernie Randolph  
Definitely for King said.

0:44:50.220 --> 0:44:51.180  
Ernie Randolph  
They're up to speed.

0:44:54.720 --> 0:44:54.880  
Ernie Randolph  
Hello.

0:44:54.90 --> 0:44:57.200  
Cody Sole  
So I think you broke out when you said you had a terrible experience.

0:44:58.40 --> 0:44:59.140  
Ernie Randolph  
I had terrible.

0:44:59.250 --> 0:45:4.80  
Ernie Randolph  
Was just the actually development, validation quality.

0:45:5.930 --> 0:45:7.380  
Ernie Randolph  
Yeah, the area Bility.

0:45:8.10 --> 0:45:12.280  
Ernie Randolph  
Umm, just not being able to perform on time.

0:45:12.390 --> 0:45:13.570  
Ernie Randolph  
That's been a big problem.

0:45:14.700 --> 0:45:15.960  
Cody Sole  
OK, turn around time then.

0:45:16.990 --> 0:45:17.790  
Ernie Randolph  
It's it's.

0:45:17.800 --> 0:45:19.600  
Ernie Randolph  
It's it's more than turnaround talk.

0:45:22.350 --> 0:45:22.720  
Cody Sole  
Ohca.

0:45:19.790 --> 0:45:28.400  
Ernie Randolph  
It's like across the board it's it's across the board, so I had.

0:45:27.260 --> 0:45:32.620  
Cody Sole  
OK, so quality and umm below moments turn all the time.

0:45:32.630 --> 0:45:35.700  
Cody Sole  
OK, so everything is not pleasant, OK.

0:45:34.290 --> 0:45:37.0  
Ernie Randolph  
O and and and and I will.

0:45:37.70 --> 0:45:40.230  
Ernie Randolph  
I will say that CompanyABC has been extremely good.

0:45:41.10 --> 0:45:41.190  
Cody Sole  
OK.

0:45:44.690 --> 0:45:45.30  
Cody Sole  
Umm.

0:45:47.770 --> 0:45:48.320  
Cody Sole  
Yes.

0:45:48.370 --> 0:45:48.680  
Cody Sole  
Uh.

0:45:41.600 --> 0:45:48.930  
Ernie Randolph  
I've worked with them and digital pathology and you gave me another one on the list that I've also been.

0:45:48.690 --> 0:45:50.600  
Cody Sole  
Another one is immune analytics.

0:45:51.780 --> 0:45:52.360  
Ernie Randolph  
I see.

0:45:52.500 --> 0:45:54.290  
Ernie Randolph  
Yeah, another very good.

0:45:54.640 --> 0:45:59.440  
Ernie Randolph  
So I have worked with him and have had very good experience, mainly in drug discovery.

0:46:1.90 --> 0:46:6.550  
Cody Sole  
O OK, is there other particular tools such or technologies that you use from immune analytics?

0:46:10.180 --> 0:46:11.870  
Cody Sole  
OK, OK, got it.

0:46:7.0 --> 0:46:12.90  
Ernie Randolph  
Well, I I guess it's primarily genomics technology and.

0:46:12.200 --> 0:46:14.620  
Ernie Randolph  
And I don't think it doesn't sound like you're interested in that.

0:46:15.540 --> 0:46:17.120  
Cody Sole  
No, no, we we definitely are.

0:46:17.130 --> 0:46:22.590  
Cody Sole  
But we're trying to balance difference bomb marker segments for considering.

0:46:22.660 --> 0:46:26.30  
Cody Sole  
So you did mention use genomics across the boards.

0:46:26.100 --> 0:46:28.920  
Cody Sole  
Have you considered genomics from CompanyABC as well?

0:46:30.590 --> 0:46:33.120  
Ernie Randolph  
I don't think that they're really is sequencing company.

0:46:33.840 --> 0:46:34.100  
Cody Sole  
OK.

0:46:35.60 --> 0:46:41.30  
Cody Sole  
So the digital pathology for sure and precision medicine, did you also use for genomics?

0:46:39.980 --> 0:46:42.840  
Ernie Randolph  
I we we did.

0:46:42.890 --> 0:46:45.860  
Ernie Randolph  
I miss Precisionmedicine develop IT.

0:46:46.670 --> 0:46:47.480  
Cody Sole  
Was it just OK?

0:46:47.660 --> 0:46:53.830  
Ernie Randolph  
It's and and and to develop Multiplex assays and just has no luck.

0:46:54.950 --> 0:46:55.300  
Cody Sole  
OK.

0:46:54.730 --> 0:46:57.650  
Ernie Randolph  
Umm I I think, yeah.

0:46:57.660 --> 0:46:58.50  
Ernie Randolph  
We've been.

0:46:58.60 --> 0:47:2.790  
Ernie Randolph  
I've been let down and the reason why I went to them was largely because I was.

0:47:2.800 --> 0:47:10.860  
Ernie Randolph  
I've been so impressed over the years in their clinical group and just do not.

0:47:12.360 --> 0:47:15.140  
Ernie Randolph  
I have not had great experience with them and others.

0:47:16.830 --> 0:47:18.340  
Cody Sole  
OK, got it.

0:47:18.640 --> 0:47:29.240  
Cody Sole  
And how important, if the CRO, either cell Carta or immune analytics, also provides assistance with companion diagnostics?

0:47:31.120 --> 0:47:32.410  
Ernie Randolph  
I'm sorry, could you say that again?

0:47:33.540 --> 0:47:33.870  
Cody Sole  
Yes.

0:47:34.140 --> 0:47:43.910  
Cody Sole  
So how important if the CRO, such as cell Carta or immune analytics, provides companion diagnostics capability?

0:47:43.920 --> 0:47:45.880  
Cody Sole  
Working with sponsors like you.

0:47:47.610 --> 0:47:58.150  
Ernie Randolph  
I'm not understanding your question, maybe I didn't hear it properly, but we start partnering, I mean, successful partnerships are really early.

0:47:58.370 --> 0:48:1.460  
Ernie Randolph  
So you have to really partner with them.

0:48:2.500 --> 0:48:14.730  
Ernie Randolph  
Umm, in in early drug development and and and then you know that will lead to validation and and further O.

0:48:17.890 --> 0:48:19.120  
Ernie Randolph  
I once one second.

0:48:20.540 --> 0:48:21.130  
Ernie Randolph  
Yeah, I got you.

0:48:21.140 --> 0:48:21.480  
Ernie Randolph  
I got you.

0:48:21.550 --> 0:48:21.780  
Ernie Randolph  
Yeah.

0:48:21.790 --> 0:48:23.840  
Ernie Randolph  
So I I always think. Ohh.

0:48:23.850 --> 0:48:24.130  
Ernie Randolph  
Perfect.

0:48:26.720 --> 0:48:28.250  
Ernie Randolph  
Umm, I'm sorry.

0:48:28.260 --> 0:48:29.960  
Ernie Randolph  
I'm I've been disrupted.

0:48:30.740 --> 0:48:31.150  
Ernie Randolph  
I'm.

0:48:30.880 --> 0:48:31.200  
Cody Sole  
Norris.

0:48:31.640 --> 0:48:35.240  
Ernie Randolph  
I just, I mean, I think I think what we we work with them.

0:48:40.240 --> 0:48:41.140  
Ernie Randolph  
Yes, thank you.

0:48:42.510 --> 0:48:45.140  
Ernie Randolph  
I'm just on the phone, so I'm.

0:48:45.750 --> 0:48:47.380  
Ernie Randolph  
I'm sorry there's been some disruption.

0:48:47.390 --> 0:48:53.920  
Ernie Randolph  
I'm just trying to umm, we we we work with them for early.

0:48:53.930 --> 0:49:1.710  
Ernie Randolph  
So during the discovery and and then we follow being that would be the month of perfect ways because they can validate.

0:49:5.30 --> 0:49:22.350  
Ernie Randolph  
I was thinking back up data because they can validate assays early and but most of the time we will will actually work with many of the companion diagnostic companies later in the game.

0:49:24.70 --> 0:49:24.320  
Cody Sole  
Hmm.

0:49:23.410 --> 0:49:33.350  
Ernie Randolph  
So we're kind of racing to them to validate assets early when they it takes long time validate assays quickly when it takes a long time to do that.

0:49:35.640 --> 0:49:37.590  
Cody Sole  
OK, that sounds good.

0:49:37.500 --> 0:49:40.970  
Ernie Randolph  
I don't know if that's, don't know if that's your question, but.

0:49:41.680 --> 0:49:41.970  
Cody Sole  
Yeah.

0:49:41.980 --> 0:49:51.730  
Cody Sole  
So it sounds it's important to engage with companies early from several perspective to Co develop the campaign diagnostic together.

0:49:52.120 --> 0:49:56.380  
Cody Sole  
I guess how likely are you to switch from your?

0:49:54.810 --> 0:49:57.440  
Ernie Randolph  
Well, we we would we?

0:49:57.930 --> 0:50:40.100  
Ernie Randolph  
Ohh I I wanted to say that if we are pretty certain that of a companion diagnostic or an asset, if we're pretty certain that it is going to be linked to a drug and it's important for that company to have the experience, to have regulatory experience and to be able to fulfill the goals and fulfill the needs of you know on the the FDA in terms of the validation of the assay and in terms of so we we enter a partnership.

0:50:41.30 --> 0:50:45.540  
Ernie Randolph  
With generally with if, when, when they're when we're not just fishing.

0:50:50.250 --> 0:50:50.440  
Cody Sole  
Umm.

0:50:45.590 --> 0:51:22.530  
Ernie Randolph  
So a lot of this is fishing that I mentioned to you before, but when we're very serious about a particular task and we think it could suffice as a true companion, diagnostics for enrichment or you know for for clinical usage, umm we we work we we we would primarily wanna work with companies that have the ability to and have had the experience and getting these companion diagnostics approved and understand the FDA's requirement from a regulatory standpoint and we would actually pay them.

0:51:25.640 --> 0:51:26.70  
Cody Sole  
Right.

0:51:26.500 --> 0:51:36.990  
Cody Sole  
OK, so if there was a CRO has not done any comparing diagnostics, so there's no track record there.

0:51:37.220 --> 0:51:41.310  
Cody Sole  
Is that a definitely know to partner with them to Co develop?

0:51:42.970 --> 0:51:43.340  
Ernie Randolph  
It.

0:51:41.320 --> 0:51:46.420  
Cody Sole  
Maybe they, you know, help you with some of those technologies in genomics or I mean monitoring up front?

0:51:46.800 --> 0:51:50.290  
Ernie Randolph  
If if they have, if they certainly, it would be a risk.

0:51:52.940 --> 0:51:57.790  
Ernie Randolph  
If they have something unique then that would be a different story.

0:51:59.970 --> 0:52:1.170  
Cody Sole  
And what do you mean by unique?

0:52:2.460 --> 0:52:6.700  
Ernie Randolph  
Meaning a unique asset, something that we couldn't get anywhere else.

0:52:7.850 --> 0:52:8.140  
Cody Sole  
Umm.

0:52:7.860 --> 0:52:10.570  
Ernie Randolph  
I don't think cost is an issue.

0:52:11.430 --> 0:52:13.200  
Ernie Randolph  
I think it's experience.

0:52:13.650 --> 0:52:15.900  
Ernie Randolph  
Turn around time, you know.

0:52:15.910 --> 0:52:18.380  
Ernie Randolph  
So you want you don't wanna go?

0:52:18.390 --> 0:52:28.60  
Ernie Randolph  
It's it's it's much harder to break into the game because you know, if I've worked with the company I I've had experience with them.

0:52:28.70 --> 0:52:33.190  
Ernie Randolph  
I I I've kind of you know, so I I kind of know the risk equation and what they can deliver.

0:52:34.510 --> 0:52:35.680  
Ernie Randolph  
I know they're management.

0:52:35.690 --> 0:52:37.760  
Ernie Randolph  
I know they're project manager.

0:52:37.770 --> 0:52:39.120  
Ernie Randolph  
I know they're turnover.

0:52:39.690 --> 0:52:44.620  
Ernie Randolph  
You know they're reliability and that's just something that's very important.

0:52:47.980 --> 0:52:50.470  
Cody Sole  
It's OK, that sounds good.

0:52:51.760 --> 0:52:52.160  
Cody Sole  
Great.

0:52:52.170 --> 0:52:54.30  
Cody Sole  
And I wanna also respect your time.

0:52:54.740 --> 0:52:54.940  
Ernie Randolph  
No.

0:52:54.40 --> 0:52:56.30  
Cody Sole  
So are there any OK?

0:52:55.10 --> 0:52:56.440  
Ernie Randolph  
Ohh no, I would do I just.

0:52:56.450 --> 0:52:58.70  
Ernie Randolph  
I just hope I helped you today.

0:52:58.80 --> 0:53:4.560  
Ernie Randolph  
I I kind of feel like I, you know, I I I just hope I helped you and and I hope you're.

0:53:3.650 --> 0:53:8.650  
Cody Sole  
Well, definitely, yeah, definitely, definitely heard.

0:53:8.660 --> 0:53:10.790  
Cody Sole  
Very good and interesting.

0:53:16.20 --> 0:53:17.380  
Ernie Randolph  
And I appreciate too.

0:53:17.390 --> 0:53:19.490  
Ernie Randolph  
And and I wish.

0:53:19.500 --> 0:53:20.200  
Ernie Randolph  
I wish you the best.

0:53:10.800 --> 0:53:21.400  
Cody Sole  
Your perspective on CNS as was oncology, so really appreciate the conversation and hopefully we can and hopefully we can connect on future projects as well.

0:53:21.650 --> 0:53:22.90  
Cody Sole  
Thank you.

0:53:22.380 --> 0:53:23.150  
Ernie Randolph  
You too.

0:53:23.240 --> 0:53:23.730  
Ernie Randolph  
You too.

0:53:24.420 --> 0:53:24.710  
Cody Sole  
Thank you.

0:53:23.740 --> 0:53:24.920  
Ernie Randolph  
Thank you so much.

0:53:25.200 --> 0:53:26.880  
Ernie Randolph  
Hope you're bye.

0:53:24.720 --> 0:53:27.890  
Cody Sole  
Have a good weekend i.e.